



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

FEB 4 1986

Re: Novafil (4,224,946)  
Docket No. 85E-0550  
Novafil (4,246,904)  
Docket No. 85E-0551

The Honorable Donald J. Quigg  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

#23

Dear Commissioner Quigg:

This is in regard to two (alternative) applications for patent extension for U.S. Patent Nos. 4,224,946 and 4,246,904, filed by American Cyanamid Co. under 35 U.S.C. § 156. We have reviewed the dates contained in the applications and have determined the regulatory review period for Novafil, the medical device claimed by the patents.

The total length of the regulatory review period for Novafil is 1251 days. Of this time, 872 days occurred during the testing phase of the regulatory review period and 379 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device began: April 30, 1982.

FDA has verified that clinical testing began on April 30, 1982, the date an investigational device exemption (IDE) became effective for the product.

2. The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: September 17, 1984.

The applicant claimed that the approval phase began on September 14, 1984. However, FDA did not receive the premarket approval application (No. P840041) until September 17, 1984.

3. The date the application was approved: September 30, 1985.

FDA has verified that application no. P840041 was approved on September 30, 1985, as stated by the applicant.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude half of the testing phase as required by 35 U.S.C. § 156(c)(2).

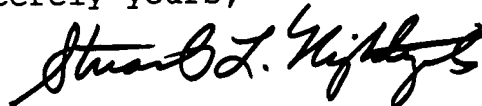
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Please let me know if we can provide further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Stuart L. Nightingale", with a stylized flourish at the end.

Stuart L. Nightingale, M.D.  
Associate Commissioner  
for Health Affairs

cc: Mr. John J. Hagan  
American Cyanamid Co.  
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